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REMARKS

Reconsideration of the present application as amended is requested. The election requirement from the first action was maintained in the present Office Action. Thus, Applicants have canceled the claims 98-116, 119-120 and 122-124 which had been withdrawn from consideration, without prejudice to presentation in a continuing application.

An obviousness-type double patenting rejection was issued with respect to Applicants' U.S. Patent No. 6,595,998. An appropriate Terminal Disclaimer will be filed upon an indication of allowability of claims in the present application.

Claims 129 and 201-203 were rejected under Section 112 as indefinite. Applicant has amended each of these claims to replace the term "column" with the term "structure" which has antecedent basis in parent claim 117. A further objection was raised with respect to the use of the terms "top" and "bottom" in claims 201-203. Applicants have amended these terms to "top-most" and "bottom-most". In any stack of elements, there must be a top-most element and a bottom-most element. Thus, these defined elements are inherent in the expandable structure defined in claim 117, so the requirements of 35 U.S.C. 112 are met.

The pending claims 117, 118, 121, 125-129 and 204 were rejected as anticipated by U.S. Patent No. 5,192,327 to Brantigan. The Brantigan implant is not configured for consecutive insertion of the modular elements. Each plug 11 includes a central aperture 11d and slots 11e that are packed with bone graft material. (Col. 4, lines 50-56). The bone graft material cannot be packed into the Brantigan plugs 11 after they have been inserted into the vertebral space. Furthermore, in the embodiments of Figures 1, 3, 4 and 5, the plugs include a connecting bar 15 that is inserted into the middle of the stack of plugs "to lock the components in fixed relation." (Col. 2, lines 59-61; col. 4, lines 25-30). The connecting bar 15 "has a height conforming to the total height of the stack of plugs ... or with only a single plug 11 if a stack of plugs is not necessary." (Col. 4, lines 38-41). Clearly, the connecting bar cannot be inserted into the stack after any plug has been positioned within the vertebral space. Moreover, this excerpt explains that Brantigan only contemplates a single implant being inserted into the space, whether that implant includes one plug or a stack of plugs. This feature of Brantigan is substantiated by the discussion at col. 2, lines 34-44, in which it is explained that the Brantigan prosthesis may be provided in different stacked heights depending upon the surgical procedure.

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Finally, the ridges 12 on the Brantigan plug 11 are aligned transverse to the direction of insertion of the plugs, as seen by comparing the orientation of the ridges 12 to the threaded holes 13, 23 that receive a mounting tool 73. (E.g., Figure 4). Figure 13 demonstrates the insertion direction of a plug, and it can be seen that the ridges are transverse to that direction. The transverse ridges would prevent one plug from being consecutively inserted on top of or beneath a previously inserted plug.

Thus, the Brantigan reference does not disclose an apparatus comprising a plurality of elements in cooperative contact that are configured for consecutive insertion between tissue surfaces. Applicants have amended claim 117 to further highlight this distinction. Amended claim 117 defines the elements as forming an expandable structure between the tissue surfaces, with each element being configured for consecutive individual receipt between the surfaces to thereby expand the structure and distract the tissue surfaces. The Brantigan implant does not meet any of these limitations in claim 117. As explained above, the Brantigan plugs are not configured for individual consecutive receipt into the vertebral space. Since the Brantigan plugs are not individually inserted, the plugs are not configured to distract the tissue surfaces.

Although the term "distraction" is not expressly mentioned in the '317 Patent, it is indicated that the disc annulus is stretched so that the vertebrae can engage a disc replacement plug. (Col. 2, lines 59-66). Brantigan further states that, "During surgery, the spinal column is stretched to regain any lost disc space ...", and that "This stretches the remaining disc tissue and ... the plugs ... are inserted into the opened up disc space ...". (Col. 6, lines 59-65). Thus, it is apparent that Brantigan does not contemplate that the plugs 11 would be capable of distracting tissue surfaces, as required by Applicants' claim 117.

Claims 117 and 201-203 were further rejected as anticipated by U.S. Patent No. 5,645,599 to Samani. The Samani reference suffers from the same deficiencies as Brantigan noted above. Specifically, the components of the interspinal implant of Samani are not configured for consecutive receipt between tissue surfaces. Instead, the Samani implant includes a bearing cushion 15 that is fixed between the upper and lower branches 5b of the implant 1, preferably by adhesive bonding. (Col. 4, lines 44-48). Moreover, it can certainly be appreciated that the cushion 15 must be fixed to the implant to prevent the cushion from being ejected as the spinal column flexes. Like the Brantigan implant, the Samani device is not configured for consecutive individual insertion of the components of the implant. Moreover, the Samani

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implant is not configured to distract the vertebral bodies. Instead, the Samani implant requires that the spinous processes of the adjacent vertebrae be moved slightly apart to engage the implant between them. (Col. 2, lines 52-57). Moreover, it is unclear whether a device positioned between adjacent spinous processes can distract the disc space between vertebral bodies.

Thus, neither the Brantigan nor the Samani reference can anticipate Applicants' claim 117 because both references fail to disclose every element recited in that claim. Specifically, neither reference discloses or contemplates an expandable structure formed by the plurality of elements, or each element being configured for consecutive individual receipt between tissue surfaces, or the plurality of elements that are configured to expand the structure and distract the tissue surfaces. Moreover, for the reasons explained above, neither Brantigan nor Samani contemplates any modification that would allow the devices in these patents to meet the limitations in Applicants' claims.

Applicants have presented new claims 205-216 that are directed to a method for distracting tissue surfaces. New independent claim 205 parallels apparatus claim 117 in the recitation of a plurality of elements that are consecutively individually introduced into contact with each other to form an expandable structure between tissue surfaces. The plurality of elements distract the tissue surfaces. Thus, the method steps recited in claim 205 cannot be practiced with an apparatus that is materially different from the apparatus defined in claim 117. Likewise, the apparatus of claim 117 cannot be used to practice a materially different process than defined in claim 205. Therefore, the new claims 205-216 can be properly considered with the pending claims under review.

New independent claim 205 defines the steps of sequentially individually introducing a plurality of elements to form an expandable structure and distract opposite tissue surfaces. As explained above, neither Brantigan nor Samani discloses a device capable of performing these steps. In particular, there is nothing in either reference that discloses or suggests individual consecutive insertion of a plurality of elements to distract tissue surfaces.

In view of the foregoing arguments and amendments, it is believed that all of the pending claims 117, 118, 121, 125-129 and 201-216 are allowable over the art of record. Action toward a Notice of Allowance is earnestly requested.

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Respectfully Submitted,



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